

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED THERAPIES
PRODUCTS LIABILITY LITIGATION

As to All Related and Member Cases

Case No.: 13md2452 AJB (MDD)

**ORDER GRANTING
DEFENDANTS' JOINT OMNIBUS
MOTION TO SEAL CERTAIN
CONFIDENTIAL DOCUMENTS**
(Doc. No. 3891)

I. INTRODUCTION

Before the Court is Defendants' omnibus motion to seal certain confidential documents related to motions for summary judgment and motions to exclude experts. (Doc. No. 3891.) Plaintiffs filed an opposition to the motion, to which Defendants replied. (Doc. Nos. 3893, 3901.) For the reasons set forth, the Court **GRANTS** Defendants' motion.

II. LEGAL STANDARD

Courts have historically recognized a "general right to inspect and copy public records and documents, including judicial records and documents." *Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 597 & n.7 (1978). "Unless a particular court record is one 'traditionally kept secret,' a 'strong presumption in favor of access' is the starting point. *Kamakana v. City and Cnty. of Honolulu*, 447 F.3d 1172, 1178 (9th Cir. 2006)

(quoting *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1135 (9th Cir. 2003)). To overcome this strong presumption, a party seeking to seal a judicial record must articulate justifications for sealing that outweigh the public policies favoring disclosure. *See id.* at 1178–79. In turn, the court must “conscientiously balance the competing interests” of the public and the party who seeks to keep certain judicial records secret. *Id.* After considering these interests, if the court decides to seal certain judicial records, it must “base its decision on a compelling reason and articulate the factual basis for its ruling, without relying on hypothesis or conjecture.” *Id.* (citing *Hagestad v. Tragesser*, 49 F.3d 1430, 1434 (9th Cir. 1995)). The strong presumption of access to judicial records applies fully to dispositive pleadings, including motions for summary judgment and related attachments. Thus, to warrant sealing documents in connection with a dispositive motion, the party must show “compelling reasons.” *Kamakana*, 447 F.3d at 1179. Relevant factors include the “public interest in understanding the judicial process and whether disclosure of the material could result in improper use[.]” *Pintos v. Pacific Creditors Ass’n*, 605 F.3d 665, 659 (9th Cir. 2010) (citations omitted).

Courts have long acknowledged that the risk of competitive harm through disclosure of confidential and proprietary information warrants maintaining documents under seal, even in light of the general presumption of public access to judicial documents. *See Nixon*, 435 U.S. at 598 (the court may ensure its records are not used “as sources of business information that might harm a litigant’s competitive standing”); *Valley Broadcasting Co. v. U.S. District Court*, 798 F.2d 1289, 1294 (9th Cir. 1996) (noting considerations that weigh against disclosure include “the likelihood of an improper use, including . . . trade secret materials; infringement of fair trial rights of the defendants or third persons; and residual privacy rights”) (internal quotation and citation omitted); *Sullivan v. Deutsche Bank Americas Holding Corp.*, No. 08CV2370, 2010 WL 3448608, at *2 (S.D. Cal. Aug. 31, 2010) (finding the “likelihood of improper use by competitors and the proprietary nature of the confidential information” was a compelling reason to seal documents).

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1 In an unpublished opinion, the Ninth Circuit has defined a trade secret in the context
 2 of a motion to seal as “any formula, pattern, device or compilation of information which is
 3 used in one’s business, and which gives him an opportunity to obtain an advantage over
 4 competitors who do not know or use it.” *In re Elec. Arts, Inc.*, 298 Fed. Appx. 568, 569
 5 (9th Cir. 2008) (quoting Restatement of Torts § 757, cmt. b). Other courts applying this
 6 definition have concluded that detailed product-specific financial information, customer
 7 information and internal reports are appropriately sealable under the compelling reasons
 8 standard where that information could be used to the company’s competitive disadvantage.
 9 *Apple Inc. v. Samsung Electronics Co., Ltd.*, 727 F.3d 1214, 1226, 1228 (Fed. Cir. 2013);
 10 *see also Asetek Danmark A/S v. CMI USA, Inc.*, No. 13CV00457, 2015 WL 4116738, at
 11 *2 (N.D. Cal. July 7, 2015). Similarly, courts have maintained documents under seal where
 12 the information contained therein could permit competitors to “gain access to operational
 13 and personnel information, projections and modeling, and strategic positioning vis-a-vis
 14 its competitors.” *Rich v. Shrader*, No. 09CV652, 2013 WL 6190895, at *2 (S.D. Cal. Nov.
 15 26, 2013).

16 **III. DISCUSSION**

17 With their joint omnibus motion to seal, Defendants seek to maintain under seal
 18 Novo Nordisk’s (“Novo”) non-published nonclinical liraglutide studies, non-published
 19 exploratory Zucker Diabetic Fatty (“ZDF”) rats analysis, 2014 liraglutide white paper,
 20 internal company strategy communications and documents concerning clinical
 21 development, confidential FDA communications, LEADER advisory committee meeting,
 22 and FDA audit preparations, and semaglutide analysis; Merck’s confidential FDA
 23 communications, and internal emails and other documents relating to desfluorositagliptin;
 24 and portions of the parties’ memoranda which refer to the aforementioned material. (Doc.
 25 No. 3891-1 at 2.)¹ Plaintiffs do not oppose the sealing of these documents—except for
 26 Novo’s ZDF exploratory analysis and 2001 ZDF study, and Merck’s documents
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28 ¹ The pinpoint page citation refers to the ECF-generated page numbers that appear at the top of each filing.

1 concerning desfluorositagliptin. (Doc. No. 3893 at 2.) Specifically, Plaintiffs argue that
2 Defendants' interest in sealing these documents are outweighed by the FDA's and public's
3 interest "in learning the important safety information Defendants have concealed." (*Id.* at
4 5.) Defendants contend that there is a significant risk that public disclosure of these
5 sensitive and proprietary materials could cause commercial harm to Defendants and
6 provide incomplete and misleading information as to the safety of their products. (Doc. No.
7 3901 at 2–3.) Upon review of the parties' briefs and declarations in support thereof, the
8 Court finds Defendants have established compelling reasons to maintain the information
9 at issue under seal.

10 At the outset, the Court notes that outside of this litigation, Defendants are avid
11 competitors of each other and of other companies in the highly competitive pharmaceutical
12 industry for diabetes medicines. *See Pub. Citizen Health Rsch. Grp. v. Nat'l Institutes of*
13 *Health*, 209 F. Supp. 2d 37, 47 (D.D.C. 2002) ("The pharmaceutical industry is a highly
14 competitive market where companies routinely attempt to discover a possible advantage
15 over their competitors."). As such, the Court credits with substantial weight Defendants'
16 assertions that disclosure of certain sensitive and propriety information would pose a
17 significant risk of commercial harm. *See Nixon*, 435 U.S. at 598; *Valley Broadcasting Co.*,
18 798 F.2d at 1294; *Sullivan*, No. 08CV2370, 2010 WL 3448608, at *2. And as previously
19 mentioned, Plaintiffs do not contest—and the Court agrees—that particular documents²
20 that Defendants wish to maintain under seal include proprietary research and data, internal
21 regulatory and safety analyses, and confidential regulatory strategies and communications,
22 which, if disclosed, could cause significant competitive harm to Defendants. Consequently,
23 because Defendants' interest in safeguarding these competitive business materials
24 overcomes the general presumption of public access, the Court will maintain these
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26 ² These documents are Novo's 2014 liraglutide white paper, internal company strategy communications
27 and documents concerning clinical development, confidential FDA communications and meetings,
28 LEADER advisory committee meeting, and FDA audit preparations, semaglutide analysis, non-published
nonclinical liraglutide studies other than the 2001 ZDF study report and the exploratory ZDF analysis,
and Merck's confidential FDA communications.

1 documents under seal.

2 Turning to the contested materials, the Court notes that Plaintiffs' arguments against
3 continued sealing of Novo's ZDF studies, Merck's desfluorositagliptin data, and related
4 documents largely reassert the claims in their summary judgment briefs that Defendants
5 have concealed material health and safety information from the FDA and public. The
6 Court, however, has considered these materials and found them insufficient to establish
7 reasonable evidence of a causal link between incretin-based therapies and pancreatic
8 cancer. As such, there appears to be little value to the public in releasing these documents.
9 Thus, disclosure of these confidential and proprietary information would more likely
10 mislead the public about the drugs' safety than serve a general interest in public health or
11 access.

12 With respect to Novo's ZDF exploratory analysis and 2001 study report, the
13 supporting declaration states that such nonclinical proprietary research "goes to the heart
14 of its business" and "is oft performed under confidential conditions." (Doc. No. 3891-2 at
15 4–5.) Moreover, the exploratory ZDF analysis contains "unfinalized information about the
16 safety profile of Victoza" and its findings "are subject to numerous limitations and lack
17 appropriate context." (*Id.* at 4.) Further, Novo determined that the data from these animal
18 studies did not warrant submission to the Federal Food and Drug Administration as they
19 were too preliminary to interpret without replication or other investigation and did not
20 suggest a significant risk in humans. (Doc. No. 3901 at 3.) Indeed, the Court came to a
21 similar conclusion in ruling on Defendants' motion for summary judgment based on
22 preemption. As such, these scientific data and evaluations bring a significant risk of
23 confusion to the public if disclosed in the limited context of adversarial motions for
24 summary judgment and motions to exclude. Thus, disclosure of these confidential
25 proprietary research may result in more harm than good by misleading the public about
26 liraglutide's safety profile. Consequently, the Court finds the threat of competitive harm
27 from disclosure and the potential to confuse and mislead the public outweigh the public's
28 right of access and amount to compelling reasons to maintain the information at issue under

1 seal. *See Foran v. Ulthera, Inc.*, No. 1:20-cv-00267-DAD-BAM, 2020 WL 3047789 at *2
 2 (E.D. Cal. Jun. 8, 2020) (finding “compelling reasons” to seal “confidential commercial
 3 information” including “analysis of clinical trials, preclinical trials and testing, as well as
 4 product development and information about the technical characteristics and testing of the
 5 product.”).

6 With respect to Merck’s desfluorositagliptin data, the supporting declaration states
 7 that such data and related internal documents contain trade secrets and proprietary business
 8 information. (Doc. No. 3891-6 at 17.) Additionally, “[t]he commercial sensitivity of these
 9 documents is compounded because they relate to a proprietary chemical compound not
 10 available for public use, not at issue in this litigation, and containing trade secret
 11 information which could benefit Merck’s competitors.” (*Id.* at 18.) As the Court found in
 12 ruling on Defendants’ motion for summary judgment based on preemption, there is no
 13 evidence that non-human studies pertaining to desfluorositagliptin, a drug different in
 14 molecular nature to sitagliptin, necessarily amount to reasonable evidence that sitagliptin
 15 causes pancreatic cancer. The public would therefore gain little from this data. Importantly,
 16 because the documents at issue relate to Merck’s propriety molecule, as well as its
 17 decision-making policies and procedures concerning when to use a marketed compound
 18 versus a propriety molecule not for human use when conducting animal studies, disclosure
 19 would readily expose Merck’s internal data and processes to improper use and significant
 20 competitive harm from competitors. *See Sullivan*, No. 08CV2370, 2010 WL 3448608, at
 21 *2; *Rich*, No. 09CV652, 2013 WL 6190895, at *2. Consequently, the Court finds the threat
 22 of competitive harm from disclosure and the potential to confuse and mislead the public
 23 about sitagliptin’s safety profile outweigh the public’s right of access and amount to
 24 compelling reasons to maintain the information at issue under seal.

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1 **IV. CONCLUSION**

2 For the foregoing reasons, the Court **GRANTS** Defendants' joint omnibus motion
3 to seal certain confidential documents related to motions for summary judgment and
4 motions to exclude experts. (Doc. No. 3891.) Though the Court refers to certain sealed data
5 in its omnibus order on the motions for summary judgment and motions to exclude, any
6 reference is general in nature and made to provide context to the Court's analysis.
7 Compelling reasons exist to maintain the underlying data, as well as the portions of the
8 parties' briefs and exhibits concerning that data, under seal. The same rationale, however,
9 does not apply to the Court's general reference to that data. Accordingly, the Clerk of Court
10 is instructed to seal the documents filed as "SEALED LODGED" at Doc. No. 3892.

11 **IT IS SO ORDERED.**

12 Dated: March 9, 2021


13 Hon. Anthony J. Battaglia
14 United States District Judge

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